



STATE OF TENNESSEE
BUREAU OF TENNCARE
DEPARTMENT OF FINANCE AND ADMINISTRATION
310 GREAT CIRCLE ROAD
NASHVILLE, TENNESSEE

Memo

To: Pharmacy Provider
From: First Health/TennCare
Date: November 1, 2005
Re: Withdrawal of Pemoline

Please forward or copy the information in this notice to all providers who may be affected by these processing changes.

FDA Withdraws Pemoline on October 26, 2005: The FDA has asked that Health Care professionals who prescribe Cylert® (pemoline) or any of its generics, should transition their patients to an alternative therapy. The Agency concluded that the overall risk of liver toxicity from Cylert® and generic pemoline products outweighs the benefits of use of this drug. Pemoline will remain available through pharmacies and wholesalers until supplies are exhausted; after which, no additional product will be available. In May 2005, sales and marketing of the brand product, Cylert®, was ceased by the manufacturer Abbott in the U.S; however, generic production continued until now.

The Bureau of TennCare would like to inform providers that any prescriptions for Cylert® and generic pemoline products (including those for patients with existing PAs) will not adjudicate for remaining stock without another PA. Claims transmitted for Cylert® and generic pemoline will deny at point of sale with the NCPDP error message of "70 - NDC Not Covered" and a supplemental message stating "Drug Withdrawn by FDA".

Prior authorizations for pemoline can be given to allow tapering of patients off pemoline and onto a preferred agent. Supplies are still available but once these supplies are diminished, no more drug will be available. Letters to prescribers of pemoline will be sent out explaining that pemoline is being withdrawn, stating the reasons why, explaining what other options are available for these patients, and explaining the changes in the prior authorization process that will now be in place for this drug. Please have providers contact the First Health Clinical Call Center at 866-434-5524 for additional information or to get a prior authorization.

Thank you for your participation in the TennCare program and your commitment to assist your patients.